Questions & Answers about
Clinical and Translational Science Awards

I. PURPOSE AND VISION:

What changes are being made to the NIH extramural clinical research program?
NIH has launched a new program designed to transform clinical and translational research, so that new medical treatments can be developed more efficiently and delivered more quickly to patients. The institutional Clinical and Translational Science Awards (CTSAs) program will create academic homes for the discipline of clinical and translational science, encourage development of novel methods and approaches to clinical and translational research, enhance informatics and technology resources, and improve training and mentoring to ensure that new investigators can navigate the increasingly complex research system. NIH grants will support the creation of these homes for the discipline of clinical and translational research at academic health centers around the country.

Why are these changes necessary? What is the problem that this new direction is trying to address?
NIH has heard at many forums and from many people (Association of American Medical Colleges (AAMC), the Institute of Medicine (IOM), deans, training directors, etc.) that bold new approaches are needed to speed the translation of scientific discoveries into treatments and cures for the 21st Century. These groups have identified obstacles with the current approach to conducting clinical research that include:

- Fragmented training programs
- Difficulty recruiting and retaining clinical and translational researchers
- Increasing regulatory burden and increasing overhead costs
- Inadequate informatics

In an attempt to address these and other concerns raised by the research community, the NIH has funded facilities, resources - such as General Clinical Research Centers, grants for individual or institutional training and mentoring, support for disease-specific centers, clinical trial networks, and training of generations of translational scientists. However, concerns have persisted in the research community that clinical and translational research needs greater attention.

What will be the benefit of this new plan/direction to research?
This new approach will provide institutions with an academic home and the integrated resources needed to advance clinical and translational science. Institutions will have greater flexibility to develop clinical and translational resources and enhance training programs to meet their needs. It will enable them to nurture a cadre of well-trained investigators who will be well positioned to make the next breakthroughs in science. It will also provide researchers with opportunities to speed the translation of basic research into clinical trials, serving our ultimate goal of enhancing the quality of care and improving health outcomes for patients with both rare and common diseases.

Is the vision to bring all academic centers to a certain minimum function level, or is the vision for certain CTSAs to offer specific expertise, such as translating from preclinical to clinical?
The vision includes the creation of expertise, the identification of best practices and then the sharing of both expertise and best practices. The cooperative agreement between the NIH and the CTSA investigators will assist this process. At this point, applicants need to determine what resources need to be transformed, bearing in mind that what is good for one institution may not apply to another. The configuration and emphasis of a CTSA proposal is left to the applicant.

There is a strong emphasis on transformation in the RFA. However, are institutes and training programs that already have a good track record handicapped because they are not transforming as much as institutions that do not have such a good track record?
Institutions will not be penalized for having a good track record. The transformation can also be seen as creating a national standard for the conduct of clinical and translational research, a collective goal to be achieved by all CTSAs.

Is it the vision that the CTSAs will revolve around a disease theme or clinical research in general?
The CTSA program was developed from an NIH Roadmap initiative, supported by all institutes at NIH, so it will not revolve around a particular disease theme. The program is intended to provide support and infrastructure for a general emphasis on clinical and translational research.

Could nanoengineering or engineering be involved as well as nutrition departments in the CTSA?
Yes, and if a CTSA application proposes to include these fields, a description of how they will contribute to the overall CTSA should be provided.

It appears that medical schools and health science centers would not be considered to encompass the entire range of clinical and translational science. What else should be included?
The full range of disciplines that would comprise clinical and translational sciences is more likely to be found at a health sciences center than a medical school alone. Examples of disciplines outside of medicine that could contribute to CTSAs include: dentistry, pharmacy, nursing, epidemiology, public health, osteopathy, bio-engineering, as well as other clinically relevant fields.

II. DEFINITIONS:

How is "translational research" defined for this RFA?
For the purpose of this initiative, "translational research" includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community.

The RFA includes two definitions of translational research. Which one is more important?
There is greater emphasis in the pre-clinical to clinical area, although the translation from clinical to community settings is also important. An institution that has strength in this second area should highlight it. Clearly different institutions will have different strengths.

III. RFA FOR INSTITUTIONAL CLINICAL AND TRANSLATIONAL SCIENCE AWARDS:

A. Funding Opportunities

If my institution does not apply this year, will there be other opportunities to apply for this program in future years?
There will be annual opportunities to apply for an institutional CTSA. However, the planning grant RFA will be issued only once, with awards to be made in FY 2006.

What is the expected timeline for making awards?
Applications will be due on March 27, 2006, and awards will be made by September 2006. A planning grant RFA (RFA-RM-06-001) has the same receipt and award dates as the CTSA RFA; however, the planning grant RFA will only be issued one time with one set of awards made at the end of FY 2006.

How will you consider universities that have many affiliates and GCRCs, each of these with an average GCRC budget in excess of $3 million? How will the budget cap work in this case? Will the entire CTSA budget be consumed by the GCRCs alone when their current budget expires?
A CTSA budget cap is calculated as the sum of support for all an institution's GCRCs, NCRR K-12 and K30 awards, and Roadmap K12 and T32 awards, to which a maximum of $6M total costs per year may be added. Funding for the new CTSA program will come, in part, from the NIH Roadmap budget and from funds redirected from existing NIH clinical and translational programs.

CTSAs are scheduled to be granted through 2012, but GCRCs are scheduled to be phased out by 2010. Will there be sites that gain a CTSA a few years after they have lost their GCRC structure?
The rate of implementation of CTSAs will depend on the funds appropriated. Since we are looking so many years ahead, it is difficult to tell precisely how many CTSAs will be implemented by a given year. However, the aim is to provide the opportunity to transition GCRCs and affiliated programs as fast as possible within the 2010-2012 timeline.

Will "CTSA supplements" be available, much like the GCRC supplements that were sometimes awarded to collaborators in the GCRCs?
No. Supplements for collaborating partners will not be awarded under the CTSA. It is expected that all projects will be integrated into the initial institutional CTSA, without using subsequent supplements for funding individual projects.

B. Eligibility

Can an institution respond to both the planning grant RFA and the CTSA RFA?
No. An institution must choose to respond to either the planning grant RFA or the CTSA RFA.

Can an institution submit more than one application in response to the CTSA RFA?
No. An institution may submit, or be part of, only a single application in response to this RFA. Multiple applications from different divisions, faculties, centers, schools, etc. of the same university or medical school will be returned without further consideration by the NIH. Institutions whose faculties hold positions at two or more universities, medical, or osteopathic schools, etc. can be part of only a single application at a time.

What institutions are eligible to apply for this award?
Eligible domestic institutions include universities, academic health centers, or other research organizations conducting clinical and translational research; however, a graduate school accredited to award higher degrees in clinical research must be included. Examples of acceptable higher degrees include M.S. and Ph.D. in topics such as Clinical Research, Public Health, Pharmacology, Nursing, and Epidemiology. Partnerships among schools of medicine, dentistry, nursing, pharmacy, osteopathy, public health, engineering, and other clinically related institutions are strongly encouraged, as is the inclusion of other relevant clinical research entities and organizations. Foreign institutions are not eligible to apply.

Can independent research institutes apply for this award?
Independent research institutes can partner with an applicant institution that is accredited to award higher degrees in clinical research.

The RFA states that "the applicant institution(s) must include a graduate school accredited to award higher degrees in clinical research." What are some examples of degrees that would be considered higher degrees in clinical research?
Examples of such degrees include, but are not limited to, M.S. and Ph.D. degrees in topics such as Clinical Research, Public Health, Pharmacology, Nursing, and Epidemiology.

For the purpose of this RFA, can a hospital or other clinical research entity be affiliated with more than one applicant institution?
No. An organization can be an affiliate in only one application.

Can my research institute link up with a university's graduate school in another city to apply?
A link among organizations in different geographic locations is allowed. However, the applicant must demonstrate that the interactions and research and training environment with such an arrangement are sufficiently strong to integrate the career development component and other key resources.

Our graduate school awards an M.S. degree in biopsychology. Will this count as a "higher degree in clinical research?"
It is the responsibility of the applicant to document that prior graduates and current students have been and are actively involved in clinical and/or translational research careers. Such evidence might be authorship of peer-reviewed publications related to

clinical or translational research, being investigator of such research grants, or similar activities.

Do I have to have a funded K12 award to be able to apply for a CTSA?
No. However, the CTSA proposal must include a K12-like component.

Do I have to include Research Education, Training, and Career Development activities in my CTSA application?
Yes, though their scale should be adjusted to your needs. The T32 component is optional.

What happens if my current K12 award has a different award date from that requested for my CTSA application?
The U54, K12, and—where applicable—T32 components of the CTSA will be reset to have the same award dates.

Can foreign institutions apply?
No.

Can a foreign institution partner with a domestic institution that is applying for a CTSA?
No.

Can institutions who do not have NIH-funded clinical research (but are industry sponsored) apply for a CTSA proposal? Will these applications/institutions be at a disadvantage?
If the applicant institution does not have any NIH-funded clinical research, it is likely that the institution is not yet ready to apply for the full CTSA and, perhaps, should consider applying for a planning grant.

In various places in the RFA, required degrees in clinical research are referred to as "Masters and Ph.D." versus "Masters or Ph.D." Please clarify: "and" or "or".
At a minimum, CTSA applicant institutions must have advanced degree awarding authority in clinical research. This could be a Masters Degree and/or a Ph.D. degree or some other advanced degree designation that has led to productive clinical research careers for graduates as documented by subsequent NIH grant support for clinical research and/or publications. As the academic home for clinical research is developed it would be advantageous to also offer a range of advanced education that will meet the needs of clinical investigators of different backgrounds.

Our institution is associated with a major medical school that has multiple hospitals as affiliates. Several of these affiliates already operate a GCRC. Would we be able to submit a separate application even though these affiliates are certain to submit one as well?
Only one CTSA application may be submitted from an institution that has higher degree awarding authority in clinical research. If more than one institution has higher degree-granting authority in clinical research, then each advanced degree-granting institution can

submit a CTSA application. However, hospitals or research institutions cannot have multiple independent affiliations with more than one degree-granting CTSA applicant institution.

Will research proposals that focus on prevention, including population-based studies be considered for the CTSA?
Yes. CTSAs are encouraged to include a broad array of disciplines in their applications and components that focus on prevention and population-based studies as well as a wide variety of translational, observational, and interventional clinical research would certainly be appropriate.

What is the potential for pharmaceutical company involvement with CTSA activities? How might individual companies be involved?
There is no set answer. Each individual institution will have to decide how to envision its relationship with these companies.

Is it advisable for schools and disciplines that normally reside outside of medical schools to participate in the CTSA?
Yes. Participation in a CTSA should bring significant benefits to all schools and disciplines involved in clinical and translational science, and all schools and disciplines should contribute greatly to developing these new homes for multidisciplinary clinical and translational science. NIH expects that bringing a wider range of clinical disciplines into an academic home (which can be a center, department, or institute) will benefit all faculty who conduct original research and teach. The goal is to develop graduate and postgraduate training curricula and programs that integrate clinical and translational science across multiple departments, schools, clinical and research institutes and hospitals.

Are specific schools / departments / disciplines encouraged to participate in the CTSA?
Yes. NIH hopes to see that the full range of schools that contributes to clinical and translational research will participate. The RFA specifically mentions schools of medicine, dentistry, nursing, pharmacy, osteopathy, public health, and engineering. The fields of biostatistics and computer science both make essential contributions, so participation by other clinically-related fields is strongly encouraged, as is the inclusion of other relevant clinical research entities and organizations.

Should programs in complementary and alternative medicine be included in the CTSA?
Yes. CTSAs are expected to provide infrastructure support for the full range of NIH-funded research. Applicant institutions are strongly encouraged to include all relevant entities that conduct translational and clinical research at their institutions.

Regarding eligible disciplines and interdisciplinary teams: Would a consortium of psychologists who conduct psychosocial experimental research, intervention and prevention clinical research, and neuropsychological investigations using fMRI, EEG, etc., meet your criteria for an interdisciplinary team? The emphasis would include the translation of biologic and psychosocial findings into improved clinical interventions.
Yes. Psychologists conducting the types of research described above would be eligible, but it would be ill-advised to limit the team to just psychologists and omit the other central disciplines (e.g., medicine, dentistry, nursing, etc.) in clinical and translational research.

Would it be appropriate to include a school of veterinary medicine in the CTSA?
Only to the extent that the veterinary school conducts research that is clinically relevant to human health, such as interventions to prevent transmission of disease from animals to humans, research on health benefits of animal companionship, as a few examples.

Is collaboration encouraged among non-related institutions? For example, can a university without a nursing school include another institution's nursing school as part of the CTSA grant?
Yes. Collaboration among non-related institutions is acceptable, and may be necessary to have a strong complement of clinically relevant schools and departments. However, the applicant will need to describe how the components and participants at the sites other than the primary applicant will contribute to and benefit from the CTSA.

Could an institution serve as a subcontractor to an application from another institution even though that institution is certain to submit an application as a lead institution?
No. An individual hospital or other institution that itself does not have degree-granting authority may only affiliate itself with a single institution that grants higher degrees in clinical research. A hospital or other entity cannot be included as a component in more than one CTSA application.

How should partners in the CTSA application be included and described?
Applicants should describe the components, governance, and structure of their center, department, or institute (C/D/I)—described below—clearly, indicating which proposed key functions will derive from the participating schools, departments, and programs.

If a partnering CTSA school or program has an existing T32 or K12 program that is not a Roadmap or NCRR initiative, will it be rolled into the CTSA of the successful applicant or will it remain outside of the CTSA for administrative and budgetary purposes?
Only NIH Roadmap and NCRR T32 or K12 awards will be rolled into the CTSA. Others will remain separate from the CTSA for budgetary and administrative purposes. However, it would be advantageous to integrate and coordinate such awards with CTSA program activities to make maximum use of institutional and NIH resources. The

programs that will be integrated into the CTSA should be described in the CTSA application.

We currently are conducting dental/medical research physically within our GCRC. Would we be able to broaden our participation in a CTSA through the use of satellite clinical research facilities, such as one physically located in the dental school.
Yes. Collaboration and integration of clinical and translational research facilities throughout the applicant CTSA institution is specifically encouraged.

C. Assembling a Home for Clinical and Translational Research

What is meant by an institutional "home" for clinical and translational research?
A "home," as defined in the CTSA RFA, can be a center, department, or institute (C/D/I), comprising faculty and programs that integrate clinical and translational science across multiple departments, schools, clinical and research institutes, and hospitals.

What components should institutions consider when building a home for clinical and translational research?
The CTSA should support the disciplines of clinical and translational science and the needs of researchers. Applicants can use the following topics relevant to clinical research as a guide but are free to develop their own list of key functions:

- Development of Novel Clinical and Translational Methodologies and Technologies
- Pilot and Collaborative Translational and Clinical Studies
- Biomedical Informatics
- Design, Biostatistics, and Clinical Research Ethics
- Regulatory Knowledge and Support
- Participant and Clinical Interactions Resources
- Community Engagement
- Translational Technologies and Resources
- Research Education, Training, and Career Development

Would it be appropriate to include the behavioral and social sciences in the CTSA?
Yes. Behavioral and social sciences are integral to clinical and translational research. By virtue of dealing with human participants, the behavioral and social sciences, as well as the biological sciences, are involved in clinical and translational research. As with all disciplines, a description of the applicant's strengths in this area and contribution of these disciplines to the overall CTSA should be provided."

Must institutions distribute funding equally through all the key activities that are described?
No. Institutions should determine what is optimal for their circumstances.

Must institutions include a patient recruitment resource?
No. The choice of resources to be offered in the application is made by the institution.

Who is the individual with broad trans-institutional authority to whom the Principal Investigator should report?
This will depend on the institution. The intent is that the PI should have the support of an individual whose authority extends to the schools participating in the application.

Can a faculty member maintain his or her primary appointment in a department and also be a full-fledged member of the CTSA center, as opposed to having the center be the sole appointment?
Yes. Institutions need to create homes for clinical research that best match their strengths and needs. Institutional commitment to a CTSA could be shown by primary appointments that came from the C/D/I. These primary appointments also could be shared with other departments.

The RFA focuses on the creation of space, primary appointments, promotions, and tenure; these are usually departmental functions. Will institutions be penalized if their applications do not propose creating a department?
There is no one answer to this. Each application will be peer reviewed and evaluated individually based on its own merit and not compared to other applications. Thus, each institution needs to determine what its specific approach will be.

Does the NIH envision the Principal Investigator being an institutional administrator, such as a vice chancellor, dean, or a program director, such as a GCRC program director?
The Principal Investigator does not need to be an institutional administrator. However, the PI must have experience—and current involvement—in clinical or translational research. The selection of the principal investigator is left up to each individual institution.

How do you envision the leadership team in the grant?
The development of the leadership team for the CTSA application is left up to the institution. However, multi- and inter-disciplinary involvement would be looked at favorably, because it would reflect an institution's intent to incorporate a diverse academic environment into the CTSA.

The RFA is clear that the PI must report directly to an official with broad trans-institutional authority. Is it acceptable for the PI to have a dual line of reporting (i.e., to report directly to a high official when fulfilling his duties as CTSA PI, but to report to a less-prominent official when fulfilling other job duties)?
The PI may report to more than one official as part of his/her institutional appointment, but it is critical that the PI have institutional authority to direct the C/D/I or other entity that comprises the home for clinical and translational science.

D. Training Components

If a CTSA applicant institution has existing T32 or K12 programs that are not Roadmap or NCRR initiatives, will these be rolled into the CTSA or will they remain independent of the CTSA for administrative and budgetary purposes?
Existing non-Roadmap and non-NCRR T32 or K12 awards will not be rolled into the CTSA. They will remain separate from the CTSA for budgetary and administrative purposes. However, applicants are strongly encouraged to integrate these awards with the CTSA to maximize the use of institutional and NIH resources in transforming clinical and translational research at their institution.

Are we limited to NCRR funded K12s and K30 and Roadmap funded T32s only or can we incorporate existing non-Roadmap/non-NCRR programs (K12, T32, etc.)?
Only the NCRR-funded K12, K30, T15, and M01 (GCRC) and the Roadmap-funded K12 and T32 are to be formally and fully incorporated (administration and budget) into the CTSA. Other K12 and T32 awards held by the applicant institution are funded by individual Institutes and Centers at the NIH and their administration and budget remain separate and distinct. However, if relevant, it would be appropriate to describe these programs and how they would interact with, contribute to, and benefit from the CTSA.

Will NCRR still be reviewing, supporting, and funding K23 and K24 awards independently of CTSAs?
Yes. These programs will be continued.

Why are K23 and K24 grant awards not being incorporated into this new award?
Since K23 and K24 grants are awarded to individuals, they will not be incorporated into this institutional CTSA. Only relevant institutional clinical research awards will be incorporated into the new institutional CTSA. Certain NCRR and NIH Roadmap awards, including the NCRR General Clinical Research Centers (M01), the NCRR K12, the trans-NIH K30, trans-NIH Programs in Clinical Research Ethics (T15), and Roadmap Multidisciplinary Clinical Research Career Development Program (K12), and Predoctoral Clinical Research Training Program (T32), support activities that are components of the institutional CTSA program.

If an institution currently has a K30 Clinical Research Curriculum Award, can it be added to the CTSA budget? Can this program be restructured?
Yes. The program could also be envisioned in new ways.

In the RFA, there are four budgets overall. If an institution already has Roadmap K12 and T32 awards, can it apply for additional funding, or will these awards be rolled into the CTSA?
A CTSA provides an opportunity to redistribute existing Roadmap K12 and T32 funds. The applicants will have to decide how they relate their budgets to their CTSA priorities.

Can existing T35s be included in CTSAs?
The T35 dollars would not fold into a CTSA, but it might be useful for the application to include information regarding any T35s the institution may have.

Will NCRR continue to make K12 awards independently of the CTSA?
NCRR plans to incorporate its K12 program into the CTSA to maintain the integration of career development with clinical research infrastructure.

The RFA allows only a total of 25 pages to describe education, career development, and research training in the application. Is this correct?
Yes. You should describe the integrated education, career development, and research training environment that you wish to create. This may involve using current programs or, more likely, configuring a new set of programs. You must give the reviewers sufficient detail for them to understand your program, how it is integrated into the CTSA, and how it will function.

Can you apply for a CTSA even if you do not have a K12 grant?
Eligibility to apply for a CTSA does not require a K12 award. In terms of the application itself, education has to permeate the activities of the CTSA. It is difficult to have an academic home unless it has a training component. Therefore, no CTSA will be made without a K12 or equivalent component. Note, however, that you can create a post-doctoral career advancement (K12) program with the CTSA funds, using additional funds supplied by the institution.

Can one copy and paste old K12 descriptions into the new CTSA grant application?
It would not be recommended. It is better to explain how the K12 program fits into the whole.

My understanding is that the goal of the CTSA should bring together all areas of clinical and translational research and research training at an institution. The Medical and Dental Scientist Training Programs (MSTP & DSTP) certainly offer excellent opportunities for clinical and translational research training, and a CTSA would most certainly serve and support the faculty and trainees engaged in these programs. How would an institution go about integrating an MSTP and/or DSTP program with the CTSA without an administrative/financial link and effectively convince the reviewers that there is indeed coordination?
Trainees would be eligible for support while registered for a Ph.D. under the T32 component of a CTSA, but they may not be supported for the years that they are registered exclusively for professional degrees, such as M.D. or D.D.S. The participation of an MSTP in the educational activities of a CTSA could be illustrated with reference to the career choices of previous trainees and with the integration of the mentoring faculty, and a letter from the MSTP program director.

Can a summer program (e.g., 10 weeks training) for medical, dental, nursing, or pharmacy students that supports experiences in clinical research be funded within the CTSA grant?
Yes. A summer program would fall under the training part of the U54.

E. Scope:

Is every institution expected to train clinical and translational researchers across the entire range of NIH-supported research, or will a focus on a restricted area be sufficient?
The range of NIH-supported research is extremely broad, so training in all of the possible areas is not required. However, research education, training, and career development should not be limited to a restricted area or discipline. The goal of the RFA is to fund a multi- and inter-disciplinary program that involves multiple components within the institution.

Do all clinical research facilities at an institution need to be included in the application for a CTSA?
While encouraged, it is not necessary to include all clinical research facilities and units in the application.

We are a specialist institute (e.g., cancer, ophthalmology, nephrology, etc.). Can we apply for a CTSA specializing in our area?
No. CTSA applications must extend to a broad range of specialties.

F. Budget

What is the anticipated budget for this new program?
It is expected that a total of approximately $30 million will be awarded to 4-7 institutions in FY 2006.

Although the financial plans of the NIH Roadmap and NCRR provide support for this program, awards are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Will this new program reduce funding for investigator-initiated (R01) research?
No. Funding for this new initiative will come in part from the Roadmap budget and existing clinical and translational programs. This will be accomplished entirely through redirecting existing resources, including Roadmap funds. Great care is being taken to preserve the investigator-initiated research support pool.

What is the expected award amount and duration?
Awards will vary in size due to the consolidation of multiple programs within the CTSA program. Applicants may request total costs up to $6 million annually for 5 years in addition to the combined current total costs of certain NIH awards (NCRR K12, K30, M01, and Roadmap T32 and K12) held by the applicant institution and its affiliates. If

successful, all of the above listed awards at each participating institution will be reconfigured into the CTSA program. Institutions without the above awards may request up to $6 million annually in total costs. For FY 2006, the anticipated number of awards from this solicitation is 4-7.

In the CTSA budget, will all nine schedules that are part of a GCRC application be needed, including an outline of all the ancillaries per protocol?
Those were required for the GCRC applications but are not required for the CTSAs. However, even though the schedules are not required, applicants will still have to justify all the funds they are requesting.

In the CTSA, there are essentially four budgets: U54, T32, K12, and a composite budget. If an institution already has a Roadmap K12 and T32, can it apply for additional funds under that mechanism, or will these programs be rolled into and replaced by the CTSA?
The K12, T32, and GCRC budgets should be added together. However, the institution then decides how it will redistribute those funds on the application, based on the institution's vision.

Please clarify how the budgeting process should work in terms of F&A? Should we use our standard institutional F&A rate or the standard GCRC F&A rate for the U54?
You would use your standard institutional F&A rate for the U54 component. Note that certain costs (e.g., clinical care) are excluded from F&A.

How many CTSAs will be funded in the years prior to 2012? Is the $500 million an incremental target or a goal?

The program's expansion rate will depend on appropriated funds. NIH expects to increase the number of awards annually so that, by 2012, 60 CTSAs will receive a total of approximately $500 million per year.

Will the ceiling of $6 million increase in total costs be guaranteed in future reissues of the RFA?
In FY 2006, the ceiling amount for an individual increase over current awards is $6 million. Budgets will be subjected to peer review and, where necessary, programmatic adjustment. Funds available in FY 2007 will depend on those appropriated for the purpose.

Will reapplications for CTSAs be allowed?
Amended applications will be allowed, providing they respond to comments in the prior Summary Statement.

Will the annual CTSA application dates always be in the spring?
NIH may eventually move the deadlines to earlier in the year, but the dates are not yet set.

Will subsequent grant applications from institutions awarded a CTSA be given a high priority for funding?
No. Applications submitted from CTSA institutions will not be given any higher priority than any other applications submitted to the NIH.

G. Governance

How will institutions oversee or govern their new "home" for clinical and translational research?
Institutions will need to develop an effective internal administration and governance structure that will promote the discipline of clinical and translational science. An External Advisory Committee should be constituted to provide critical, stimulating, and thoughtful advice for the overall CTSA performance. Please note that the proposed members of Advisory Committees should not be named in the application.

How will NIH oversee the institutions awarded under this new initiative?
A trans-NIH CTSA Project Team consisting of NIH staff with clinical/translational research expertise has been established to oversee the program, track and evaluate programmatic outcomes, address the needs of the other NIH Institutes and Centers, and to ensure effective coordination across the NIH.

H. Community Engagement

The RFA emphasizes community engagement. What is the thinking along these lines?
Community involvement grows out of the NIH Roadmap component of the RFA. "Community" can be defined as the academic community as well as the lay community. It is important to involve broadly all the disciplines within the academic health centers and institutions involved in clinical research. A successful application would integrate programs in various schools within the CTSA to transform the academic infrastructure of the institution. Bringing the research enterprise into the community by involving primary care providers is an important means to broadening research participation. It would also be important to involve the local lay community in the CTSA. NIH has a public trust initiative that seeks to include the lay community—as well as community advocates—as active participants in NIH initiatives.

What is the role of advocacy organizations?
Advocacy organizations can play a critical role, depending on how much they are involved in supporting or organizing research that will occurr at CTSA sites.

How do you envision the inclusion of community-based participatory research methods in the CTSA?
There are a number of new models emerging on how to approach community-based participatory research. Please note that the RFA lists a Web site that contains the reports from the Director's Council of Public Representatives (COPR). This is an advisory group to Dr. Zerhouni. Some of these reports contain many recommendations as to how the community can be involved with NIH and research.

Can you please clarify what is envisioned in terms of "community engagement"? Does this include involving community physicians in clinical research?
The NIH's COPR recently explored ways to foster community involvement in clinical research and reported their recommendations. In addition to involving community health providers in clinical research, community engagement may include overcoming the barriers to and enhancing the opportunities for public trust and participation in clinical and translational research, primarily by patients and other participants in clinical and translational research.

Descriptions of Community Engagement could include how the institution will involve the community in setting research priorities that directly affect patients, innovative ways to engage community members in mentoring processes, partnerships in clinical and translational research, and collaborations to enhance research perspectives (e.g., health disparity research), public trust, and recruitment for clinical and translational research. Additional topics include outreach plans for community practitioners including means of engagement, possible incentives, application of research results (dissemination), and plans for training CTSA researchers, trainees, and scholars in community outreach, cultural sensitivity, and population- and community-based research methods.

I. Review Criteria

Should I include a detailed description of a science project (e.g., a pilot project) in my application?
No. Reviewers will not be asked to assess the scientific merit of individual projects.

What are the metrics to be used? In the past, GCRC reviews used metrics such as the number of patient visits and the number of publications produced. Would these numbers be of value to the CTSA reviewers? How will the track records of the GCRCs be factored into the CTSA applications?
The CTSAs are new, independent awards that are very different from the GCRC awards, so they are seen as different activities altogether. Note that the RFA allows for the inclusion of Tables and other information on "Past and current funded clinical and translational research support and productivity." Prior success of a given GCRC does not predict success of CTSA applications.

There seems to be a lot of flexibility for institutions to develop metrics for continuing funding. Is this correct?
Yes. The proposal should first include a detailed self-evaluation plan to assess implementation of the short-term and long-term CTSA goals, including implementing program activities and tracking trainees and scholars and their mentors, their pilot projects, and their involvement with multidisciplinary team research. For each proposed key function, the plan should include the objectives of the evaluation or tracking activities, the principal measures or indicators, and potential data sources.

What suggestions do you have for applicants regarding cost estimation for preparing and implementing a tracking and evaluation plan for the CTSA and for participation in the national evaluation? Also, what activities are expected of applicants with respect to participation in the national evaluation?
No cost estimates are available from the NIH perspective. However, the RFA explains some of the components for the evaluation.

Can you provide more information about the potential composition of the review panel? Will the panel be comprised mostly of external reviewers?
A special review group of external reviewers will be constituted and will represent a diverse group of experienced clinical and translational researchers. The review will be administered by the NCRR Office of Review staff and reviewers will use the review criteria specified in the RFA.

IV. PLANNING GRANTS:

What if an institution is not ready to compete for the full CTSA RFA?
In FY 2006, NIH is issuing a planning grant RFA for institutions that are not yet ready to compete for a CTSA.

How many years will planning grants be offered?
The RFA for planning grants will be a one-time solicitation, and the awards will be for one year.

How many planning grants are expected to be awarded in FY 2006, and what is the expected total budget for these planning grants?
Approximately 50 planning grants, totaling approximately $11.5 million, will be awarded in FY 2006.

Can an institution apply for both the planning grant and the full CTSA grant at the same time?
No. The planning grants are for institutions that may not be ready to apply for a full CTSA grant. Planning grants supply only one year of support.

Can an organization both apply for a planning grant and be a subcontractor on a CTSA application?
No. An institution can be part of only one "home;" so, once an affiliation is made for this purpose, the institution cannot plan for a different affiliation.

Could an institution apply for a planning grant in 2006 and then a full CTSA grant in 2007?
Yes.

What do you expect to see in the planning grant applications?
Planning grants provide resources to allow institutions to develop a plan for the content, governance, administration, and evaluation of a CTSA, and to manage the necessary organizational and cultural changes to implement the program. As such, planning grants should clearly state the vision for the CTSA and propose a planning process that has potential to significantly change the way clinical and translational sciences are pursued at the institution. In other words, the planning process that will be used to prepare a future CTSA application should be described in the planning grant application, which is organized with a focus based on the institutional CTSA guidelines and review criteria.

Can you expand on the review criteria for the planning grants?
Please see detailed review criteria given in RFA-RM-06-001. These are the specific criteria that will be used in review of the CTSA applications.

Must institutions applying for CTSA planning grants have a degree-granting program in clinical research or can they propose developing it as part of this planning process?
Institutions applying for the CTSA planning grants need not have an advanced degree program in clinical research. However, applicants for the CTSA (RFA-RM-06-002) must have higher degree awarding authority.

Can an institution which does not currently have a clinical training component but which is actively planning one with potential partners be the lead institution for a planning grant?
A lead institution for a planning grant does NOT need to have all the required elements for a CTSA in place at the time of application for the planning grant. The intent of the planning grant is to provide resources to do what is necessary to develop or organize those elements not yet ready so that they are in place for an application for a full CTSA.

V. GCRC-SPECIFIC QS & AS:

If an institution with one or more GCRCs is awarded a CTSA, what happens to the GCRC(s)?
Certain NCRR and NIH Roadmap awards, including the NCRR General Clinical Research Centers (M01), the NCRR K12, the trans-NIH K30, trans-NIH Programs in Clinical Research Ethics (T15), and Roadmap Multidisciplinary Clinical Research Career Development Program (K12) and Pre-doctoral Clinical Research Training Program

(T32), support activities that are components of the Institutional CTSA program. To achieve program integration, each of these awards held by the applicant institution and its participating affiliates, but not individual K23 and K24 awards, will be relinquished at the time of award and reconfigured into the CTSA.

In FY 2006, can an institution apply for a GCRC award and a CTSA RFA award?
Institutions may not apply for a GCRC (M01) grant and a CTSA grant at the same time. Institutions are encouraged to submit a CTSA application.

In FY 2006, can an institution apply for a GCRC award and a planning grant award?
Yes. Institutions may apply for both a GCRC and a planning grant award.

If an institution with a GCRC competes for a CTSA and is not funded, what happens to the GCRC?
If the application is unsuccessful, the institution retains their current funding for the awarded project period.

What is the transitioning process for the GCRCs into the CTSA program?
This new CTSA program, which NCRR is leading on behalf of the NIH Roadmap for Medical Research, will transform and advance clinical and translational science as a distinct discipline within a definable academic home. Since the RFA will be issued annually, academic health centers, including those with GCRCs, will have the opportunity to build on their existing resources and transform into this new integrated program over a period of years. Also, a one-time planning grant RFA (RFA-RM-06-001) has been announced to give institutions more time to prepare to apply for a CTSA. The CTSA program will build on existing programs by reconfiguring, and adding to, certain NIH awards (NCRR GCRC [M01], K12, K30, and Roadmap T32 and K12) held by the applicant institution and its affiliates.

As part of this process, NCRR will modify procedures for GCRCs as follows:

- General Clinical Research Center or GCRC (M01) applications submitted in 2006 and beyond are to prepare the M01 application in accordance with the September 2005 Guidelines for the General Clinical Research Centers Program (M01). The Clinical Research Review Committee will review these applications without conducting a site visit.

- Applications that already have a scheduled submission date will continue to be accepted. Those that are successful through the review process will receive a 3-year M01 award.

- New and amended GCRC applications will continue to be accepted through January 1, 2007.

- Competing continuation GCRC applications will be accepted through June 1, 2007.

GCRCs with a project period end date in 2008 may request a 1-year extension of support for their M01 grant in lieu of a competing renewal application.

Institutions with GCRCs that are applying for a CTSA should be aware of the following:

- An institution may not simultaneously hold both a CTSA and a GCRC award. As specified in RFA-RM-06-002, successful applicants for CTSAs will relinquish their GCRC grants when the CTSA is awarded, because M01 funds will be reconfigured to become part of the CTSA. While institutions may hold more than one GCRC award, they may only hold, or participate in, one CTSA.

- In 2006, institutions may submit an M01 grant application and a CTSA Planning Grant application. However, they may submit either an M01 grant application or a CTSA grant application, but not both.

- Applicants with a GCRC (M01) grant who are unsuccessful in obtaining a CTSA will retain their current GCRC grant for the awarded project period.

When will the transitioning process for the GCRCs be completed?
NCRR anticipates that the competitive process that will transform GCRC (M01) grants to CTSAs will be complete by September 30, 2010. NCRR will work flexibly on a case-by-case basis with GCRCs during this transition period to give them time to plan and apply for a CTSA.

The CTSA program is designed to enable research but not support research directly. GCRCs currently support over 9,000 research protocols nationally, with in-kind support for hospital beds, nursing, core labs, bionutrition, etc. Many of these protocols are NIH-supported or multi-centered network studies that depend on GCRC support. Will the CTSA support these research studies?
CTSAs are meant to incorporate the kinds of activities by which GCRCs currently support the research of all the NIH Institutes. So, the GCRC nursing support, the core lab support, etc., can certainly be incorporated into a CTSA.

Is it correct to say that applications will not be requesting funding for the support of primary scientific endeavors?
Yes.

Will reviewers still need an overview, listing, or presentation of the scientific base that will be supported by the CTSA?
Applications must help reviewers understand the breadth and depth of scientific programs and how these will be integrated into the CTSA.

It was mentioned that the CTSA will not support science. However, there seems to be support for pilot awards in the RFA. Is this right?
This is correct. Also, bear in mind that the pilot projects can be larger in scale than those currently supported by GCRC M01 grants. These pilot funds can be used for a wide variety of research such as informatics research, applied research, and research into regulatory aspects or new models of safety.

In transforming GCRCs, will the nursing staff be required? Also, what is the expectation for the future use of GCRC space?
Which resources will be committed to participant or clinical interactions is a decision that needs to be made by each applicant. Nurses can be included in the budget as CTSA-supported nurses, and the RFA states that support may be requested for "the provision of in-patient, out-patient, and community-based exam rooms."

Will GCRCs become the outpatient/inpatient clinical research units of CTSAs? And, will other functions like biostatistics, nutrition, etc., also be folded into CTSAs?
The current configuration of the GCRCs is not necessarily expected to become the CTSA outpatient/inpatient clinical research units; rather, many of the clinical interaction activities that the GCRC grants currently support are likely to be appropriate for the CTSAs.

I currently have a clinical research project funded through our GCRC. How will my project be affected if my institution receives a CTSA?
Resources currently available through a GCRC could be continued through a successful proposal for a CTSA, though the prioritization of projects will rest with the awardee institution.

Can I propose current or future clinical research projects to be included in the CTSA application in the same way that I proposed them to my GCRC?
Detailed descriptions of individual research projects or pilot projects should not be included in a CTSA application. Instead, applicants can justify support for the CTSA and for pilot projects by citing their other NIH and peer-reviewed or industrial clinical research funding that they receive. Applications for CTSAs are expected to include a description of the means by which projects are selected to receive CTSA support. CTSAs specifically encourage the development of novel clinical and translational methodologies to build an environment to sustain intellectual exploration. For example, faculty members could pursue their funded research in areas that might include new translational methodologies, developing new phenotyping methods that are more objective and quantifiable, developing biomarkers for research purposes, research in clinical trial design, clinical informatics, longitudinal studies, home-based research devices and methods, predictive toxicology in human populations, and ethics research specific to various populations.

Support for pilot and collaborative translational and clinical studies may also be requested that allow clinical and translational trainees or researchers to generate

preliminary data for submission of research applications, to seek to improve clinical design, bioinformatics, regulatory pathways, clinical research ethics, develop new technologies.

VI. INVOLVEMENT of OTHER NIH INITIATIVES:

NIH has funded a number of other translational efforts in the past such as centers and cores. How will the CTSAs relate to these?
It would be helpful for applicants to describe how the CTSAs could participate in the widest range of NIH-supported activity at their specific institutions. Applicants might want to integrate currently supported translational efforts into the whole. In other words, applicants may want to integrate existing initiatives with CTSA efforts. It is important to describe how the institution as a whole will provide the best environment for clinical and translational research.

Can one degree-granting institution have several GCRC M01 grants incorporated into one application? For example, can the application include the M01 for the degree-granting institution plus the M01s from other affiliated hospitals?
Yes. The degree-granting institution can only be cited in one application; therefore, all the M01s must be added to the total for that application.

Will NCRR's Biomedical Informatics Research Network (BIRN) initiatives be rolled into the CTSAs?
During the current lifetime of the bioinformatics awards, both initiatives will exist as separate awards.

How is the use of the cooperative agreement (U54) mechanism consistent with the statement in the RFA that the applications must reflect an institutional vision?
The U54 is a cooperative mechanism whereby NIH plays a part in the institution's award. This allows activities to be coordinated across different CTSAs, which may aid in identifying and adopting best practices across the system as a whole.

Compared to other NIH initiatives, the CTSA seems to have less emphasis on science programs. Is this correct?
Yes. The CTSA is envisioned as an infrastructure award that will help the institution support research in all disciplines across the institution. This will be an underlying base that will enable other research to flourish.

How do you see the CTSA process linking to the Cancer Center programs of the National Cancer Institute (NCI), especially regarding the capabilities of free-standing centers?
NCRR is undergoing discussions with NCI to determine how NCRR resources can support NCI programs. Duplication of services between a CTSA and, for example, a Cancer Center program would be inefficient.

VII. OTHER:

Would it be appropriate for Ph.D. degrees to be granted by one of the associated departments (e.g., public health, nursing, or biomedical engineering) with an emphasis in clinical research, rather than granted by the Center for Clinical Research?
The degree-granting authority will be determined by institutional requirements. The application should describe how the educational aims of the CTSA program would be met.

Will the new NIH initiative to recognize multiple PIs apply to CTSAs – even when the co-PIs are at different institutions?
The use and recognition of co-PIs is not yet officially in place at NIH. If and when the plan to allow multiple PIs is implemented, it would be available for use with the CTSAs.

VIII. MORE INFORMATION:

Who can I contact with specific questions about this new initiative?
Programmatic questions about this new initiative should be directed to:

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